

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 64-90 are pending in the application, with 64, 71, 75, and 79 being the independent claims. Claim 64 is amended to add the word "wherein" after the first chemical formula. Claims 65-68, 72-84, and 88-90 have been indicated as withdrawn. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Restriction Requirement***

Applicant thanks the Examiner for removing the restriction requirement with respect to Groups I and II. Accordingly, the Examiner stated that "claims 64-74 and 83-88 are examined together." *See* Office Action at 2. However, on page 3 of the Office Action, the Examiner states that "[c]laims 64, 69-71, and 85-87 are examined." Application respectfully requests clarification regarding these inconsistent statements.

Applicant also notes that Applicant did respond to the Examiner's request for an election of species. On the first page of Applicant's Reply to Restriction Requirement, filed April 14, 2006, Applicant included the following paragraph:

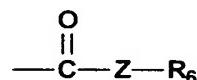
Applicant also provisionally elects the following species for initial search: DMRIE carboxylate propyl amide. This species is exemplified in Example 3. Claims 64 and 71 read on the elected species. With respect to this species, the variable groups of claim 64 are as follows: R<sub>1</sub> and R<sub>2</sub> are CH<sub>3</sub>(CH<sub>2</sub>)<sub>12</sub>C(O)-; R<sub>3</sub> and R<sub>4</sub> are CH<sub>3</sub>; R<sub>6</sub> is propyl; Z is NR<sub>1</sub>, wherein R<sub>1</sub> is H; and n and m are 1. The variable groups of claim 71 are as follows: R<sub>1</sub> and R<sub>2</sub> are CH<sub>3</sub>(CH<sub>2</sub>)<sub>12</sub>C(O)-; R<sub>3</sub> and R<sub>4</sub> are CH<sub>3</sub>; R<sub>7</sub> is H; R<sub>8</sub> is propyl; and n and m are 1.

***Rejections under 35 U.S.C. § 102(b)***

The Examiner has rejected claims 64, 69-71, and 85-87 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,459,127, issued to Felgner et al. ("the Felgner patent"). The Felgner patent is a divisional patent of U.S. Patent No. 5,264,618, which is discussed in the specification of the present application and was cited in Applicant's Information Disclosure Statement filed March 29, 2004. Applicant respectfully traverses.

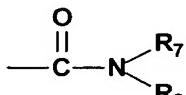
The Examiner contends that the Felgner patent teaches a compound which anticipates the claims in the present application. Applicant notes, however, that inspection of the definitions of the R groups for the claimed invention and the invention disclosed in the Felgner patent reveals that the Felgner patent does not disclose compounds claimed or described in the present application.

Specifically, the Felgner patent does not teach compounds of the present application at least because the Felgner article does not teach the limitation of claim 64 that R<sub>5</sub> has the following structure



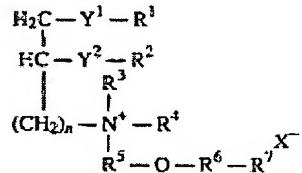
wherein Z is selected from the group consisting of O, S, NR<sub>1</sub>, NH, Se, and CR<sub>7</sub>R<sub>8</sub>, and R<sub>6</sub> can be as defined above in claim 64. Thus, R<sub>5</sub> can represent an ester or amide moiety having a particular configuration. An example of such a compound is DMRIE carboxylate propyl amide, exemplified in Example 3.

For similar reasons, the Felgner patent does not teach a compound of claim 71.



wherein  $R_5$  is  $R_8$  wherein  $R_7$  and  $R_8$  are defined as in claim 71.

The Felgner patent teaches a compound according to the following formula



*See the Felgner patent, col. 10, ll. 13-21. As explained in the Felgner patent, the substituents R<sup>5</sup>, R<sup>6</sup>, and R<sup>7</sup> in the preceding formula are defined as follows:*

$R^5$  is C<sub>1</sub> to C<sub>24</sub> alkyl straight chain or branched chain;

R<sub>6</sub> is -C(O)-(CH<sub>2</sub>)<sub>m</sub>-NH-, a diaminocarboxylic acid which is alkyl, aryl, or aralkyl, or -C(O)-(CH<sub>2</sub>)<sub>m</sub>-NH- linked to said diaminocarboxylic acid, or is absent; and

$R_7$  is H, spermine, spermidine, a histone, or a protein with DNA-binding specificity, or wherein the amines of the  $R_7$  moiety are quaternized with  $R_3$ ,  $R_4$ , or  $R_5$  groups.

*Id.* at col. 10, ll. 30-37. Thus, the compounds of the Felgner patent do not disclose or suggest the particular functional groups defined by R<sub>5</sub> in Applicant's present application.

For at least this reason, the Felgner patent does not teach each and every limitation of claims 64, 69-71, and 85-87. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

### ***Rejections under 35 U.S.C. § 103***

The Examiner has rejected claims 64, 69-71, and 85-87 under 35 U.S.C. § 103(a) as being obvious over Felgner, et al., "Enhanced Gene Delivery and Mechanism Studies

with a Novel Series of Cationic Lipid Formulations," *Journal of Biological Chemistry* 269(4):2550-2561 (1994) ("the Felgner article"). Applicant respectfully traverses.

In determining whether a claimed invention is obvious, one must take the following steps: "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). To establish a *prima facie* case of obviousness, the prior art must teach or suggest each and every element of the claimed invention. Additionally, there must be some suggestion or motivation, either in the prior art itself or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art or combine the teachings of the prior art in the matter posited by the Examiner. *See, e.g., In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006); *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000).

The Examiner has failed to establish a *prima facie* case of obviousness based on the Felgner article. The Felgner article teaches particular cationic lipid compounds. However, there is no motivation or suggestion, either explicit or implicit, in the Felgner article to make and use any of the compounds of claims 64, 69-71, and 85-87. Specifically, the Felgner article does not teach or suggest, explicitly or implicitly, a compound having a functional group corresponding to R<sub>5</sub> in claim 64.

For at least this reason, the Felgner article does not render claims 64, 69-71, and 85-87 *prima facie* obvious. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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